SEVEN HILLS COLLEGE OF PHARMACY

[AUTONOMOUS]

Venkatramapuram, Ramachandrapuram (Mandal), Chittoor (Dist), **TIRUPATI** - 517 561, A.P, INDIA

Accredited "A" Grade by NAAC, Bangalore

Awarding University: JNT University Anantapur – Ananthapuramu Approved by AICTE & PCI, New Delhi, Govt. of A.P.

Recognized by UGC Under Sections 2(f) & 12(B) of UGC Act 1956

SHCP R23 Regulations – 2023

M.Pharmacy - Pharmaceutics

COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2023-2024

(From 2023 Admitted Batch)

I YEAR - I Semester

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S01101	Modern Pharmaceutical Analytical Techniques	C	3L+1T	4	30S+10Obj	60
2	23S03101	Drug Delivery Systems	C	3L+1T	4	30S+10Obj	60
3	23S03102	Modern Pharmaceutics	C	3L+1T	4	30S+10Obj	60
4	23S03103	Regulatory Affairs	C	3L+1T	4	30S+10Obj	60
5	23S01105	Modern Pharmaceutical Analytical Techniques Practical	C	6P	**3**	30S+10Obj	60
6	23S03104	Drug Delivery Systems Practical's - I	C	6P	3	30S+10Obj	60
7	21S03105	Seminar/Assignment & Mini Project	C	1T+6P	4	100	-
8	23DAC101a 23DAC101b 23DAC101c	1. Spirituality & Value Education 2. Disaster management 3. Basic Research Skills	CBS	4L	0	50IL	-
Total				16T+19P	26	390	360

I YEAR II Semester

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S03201	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	C	3L+1T	4	30S+10Obj	60
2	23S03202	Advanced Biopharmaceutics &Pharmacokinetics	C	3L+1T	4	30S+10Obj	60
3	23S03203	Computer Aided Drug Delivery System	C	3L+1T	4	30S+10Obj	60
4	23S03204	Cosmetic and Cosmeceuticals	C	3L+1T	4	30S+10Obj	60
5	23S03205	Nano Technology & Targeted Dds (Ntds) Practicals - II	C	6P	**3**	30S+10Obj	60
6	23S03206	Advanced Biopharmaceutics & Pharmacokinetics Practicals -III	C	6P	3	30S+10Obj	60
7	23S03207	Seminar/Assignment & Mini Project	C	1T+6P	4	100	-
8	23DAC301a 23DAC302b 23DAC303c	1. Simulation tools for drug design 2. Cutting edge technologies in pharmaceutics 3. Pilot Plant and Scale-Up techniques in Pharmaceutical Dosage forms.	CBS	4L	0	50IL	-
Total				16T+19P	26	390	360

III SEMESTER

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S03301	Research Methodology and Biostatistics	C	3L+1T	4	30S+10Obj	60
2	23S03302	Teaching Assignment	C	4P	2	100	-
3	23S03303	Comprehensive viva voce	C	-	2	-	100
4	23S03304	Research Work-I	C	24P	12	100	-
5	23SPE301	Publication ethics in Research	C	3L	3	30P+10CA	60
6	23SOE302	1. Professional Business Skills	CBS	3L		50IL	60
7	23SOE303	2. IPR and Patents	CBS				-
Total				10L+28P	23	330	280

IV SEMESTER

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S04101	Journal Club	C	1L	1	25	-
2	23S04102	Research work-II	C	3L+30P	18	100	-
3	23S04103	Discussion/ Final Presentation	C	3L	3	75	200
Total					22	200	200

M.PHARMACY I YEAR I SEMESTER

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C
23S01101		4	0	0	4
	Semester	**I**			

Course Objectives:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Outcomes (CO): Student will be able to

After completion of course student is able to know about chemicals and excipients.

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

UNIT - I	11hrs	
Self-Study-	*Introduction, Theory, Laws of EMR*	

a. UV-Visible spectroscopy: Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivativespectroscopy, **Woodward's Rule and its application in determination of molecular weight of compounds.**

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT - II	11hrs	
Self-Study	*Quantum numbers and their role in NMR*	

NMR spectroscopy: Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy, **Interpretation of NMR Spectra.**

UNIT - III	11hrs	

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT - IV	12hrs	
Self-Study	*Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation*	

Chromatography- Principle, instrumentation, selection of solvents; chromatographic parameters,factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography

c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography
g) Affinity chromatography; h) Gel Chromatography
i) Hyphenated techniques:

- Ultra-High Performance Liquid chromatography- Mass spectroscopy
  - Gas Chromatography-Mass Spectroscopy
  - **UPLC and its applications**

UNIT - V	15hrs	

a. Electrophoresis: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:
i) Paper electrophoresis ii) Gel electrophoresis iii) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of X-ray diffraction.

c. Immunological assays: RIA (Radio immuno assay), ELISA, **RT-PCR**, Bioluminescence assays.

Reference Books:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
4. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
5. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
6. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
7. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
8. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
9. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
10. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
11. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley& Sons, 1982.
12. Organic Chemistry by I. L. Finar
13. Quantitative Analysis of Drugs by D. C. Garrett
14. HPTLC by P.D. Seth
15. Indian Pharmacopoeia 2007
16. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
17. Reich, Anne Schibli
18. Introduction to instrumental analysis by Robert. D. Braun

Course Code	DRUG DELIVERY SYSTEMS	L	T	P	C
23S03101		4	0	0	4
Semester		I			

Course Objectives:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Course Outcomes (CO): Student will be able to

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

UNIT - I	10hrs	
Self-Study	*Introduction & basic concepts, advantages/disadvantages*	

Sustained Release (SR) and Controlled Release (CR)formulations: Factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy, **Pelletization and design and evaluation of multiparticulate oral systems**

UNIT - II	10hrs	
Self-Study	*Principles &Fundamentals, Types*	

Rate Controlled Drug Delivery Systems: Activation Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems- Principles & Fundamentals, **Oro dispersible systems, Dissolution testing, medium selection and validation of dissolution apparatus.**

UNIT - III	10hrs	
Self-study	*Principle, concepts, advantages and disadvantages*	

Gastro-Retentive Drug Delivery Systems: Modulation of GI transit time, **Different Approaches-High density systems, floating systems, muco-adhesive systems, Expandable systems, Magnetic systems, Superporous Hydrogels, Evaluation of GRDDS**

Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

UNIT - IV	16hrs	
Self-Study	*Barriers of drug permeation, Structure of skin and barriers, Penetration enhancers*	

Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers, – **Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation, Novel ophthalmic drug delivery systems**

Transdermal Drug Delivery Systems: Transdermal Drug Delivery Systems, Formulation and evaluation, **Iontophoretic and Sonophoretic DDS, Recent advances –use of microneedles in transdermal drug delivery**

UNIT - V	14hrs	
Self-Study	*Barriers for protein delivery.*	

Protein and Peptide Delivery: Formulation and Evaluation of delivery systems of proteins and other macromolecules. **Routes for delivery of proteins and peptides with emphasis on oral and mucosal delivery, pulmonary delivery, nasal delivery and parenteral delivery**

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines

Reference Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York!Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers &Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

Course Code	MODERN PHARMACEUTICS	L	T	P	C
23S03102		4	0	0	4
Semester		I			

Course Objectives:

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Course Outcomes (CO): Student will be able to

Upon completion of the course, student shall be able to understand

• The elements of pre-formulation studies. • The Active Pharmaceutical Ingredients and Generic drug Product development • Industrial Management and GMP Considerations. • Optimization Techniques & Pilot Plant Scale Up Techniques • Stability Testing, sterilization process & packaging of dosage forms.

UNIT - I	12hrs	
Self-Study	*Theories of dispersion and pharmaceutical Dispersion*	

a. Preformation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. **SMEDDS/SNEDDS- Formulation and Evaluation,** Preparation and stability of Large and small volume parental –physiological and formulation consideration, Manufacturing and evaluation.

b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

UNIT - II	12hrs	
Self-Study	*Introduction to Pharmaceutical Validation, Scope &merits of Validation*	

Validation: Validation and calibration of Master plan, ICH& WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities, **Validation Process and Equipment in formulation development**

UNIT - III	12hrs	
Self-study	*Objectives and policies of current good manufacturing practices*	

cGMP & Industrial Management: Layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management, **Submission of Pharmaceutical Development and related information in CTD format. Relevant Examples.**

UNIT - IV	12hrs	
Self-Study	*Barriers of drug permeation, Structure of skin and barriers, Penetration enhancers*	

Compression and compaction: Physics of tablet compression, compression, consolidation, **Compaction of powders- definitions of compression & consolidation, deformation mechanisms of matter, steps in compaction of tablets (in detail), theoretical aspects, Force Volume relationships/porosity –pressure equations (Heckel's Law & equation), Granulation of powders –theory, Effect of compaction pressure on various tablet properties, Energy for**

compaction & effect of lubrication of granules, instrumentation of tablet presses (principles)effect of friction, distribution of forces, compaction profiles.		
UNIT - V	12hrs	
Self-Study	*Calculations for shelf life based on degradation kinetics*	
Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.		
Reference Books:		

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean &A.H.Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Pre-formulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III

Course Code	REGULATORY AFFAIRS	L	T	P	C
23S03103		4	0	0	4
Semester		I			

Course Objectives:

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings indifferent countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

Course Outcomes (CO): Student will be able to

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies indifferent countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

UNIT - I	12hrs	
Self-Study	*Case-studies on MSF and DMF*	

Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments, CFR (CODE OF FEDERALREGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in – vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

UNIT - II	12hrs	
Self-Study	*Case-studies on Product approval forms*	

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

UNIT - III	12hrs	
Self-study	*CDSCO Guidelines*	

CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

UNIT - IV	12hrs	
Self-Study	*Indian Drug Regulatory*	

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

UNIT - V	12hrs	
Self-Study	*Clinical Research Management*	

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee, Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

Reference Books:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/ 8. www.fda.gov/ 9. europa.eu/index_en.htm 10. https://www.tga.gov.au/tga-basics

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
23S01105		0	0	6	3
Semester		I			

List of Experiments

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Quantitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography

Course Code	DRUG DELIVERY SYSTEMS PRACTICALS - I	L	T	P	C
23S03104		0	0	6	3
Semester		I			

List of Experiments

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation
2. Formulation and evaluation of sustained release matrix tablets
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Mucoadhesive tablets.
6. Formulation and evaluation of trans dermal patches.
7. To carry out pre-formulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.
10. To study the effect of particle size on dissolution of a tablet.
11. To study the effect of binders on dissolution of a tablet.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

M.PHARM I Year II Sem

Course Code	MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)	L	T	P	C
23S03201		4	0	0	4
Semester		II			

Course Objectives:

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Course Outcomes (CO):

Upon completion of the course student shall be able to understand • The various approaches for development of novel drug delivery systems. • The criteria for selection of drugs and polymers for the development of NTDS • The formulation and evaluation of novel drug delivery systems.

UNIT - I	12hrs	
Self-Study	*Concepts, Events of drug targeting*	

Targeted Drug Delivery Systems: Biological process involved in drug targeting, Stratagies of Tumor targeting and Brain specific delivery, **Receptor mediated drug targeting, Colon targeting approaches and DDS, Biomedical applications of Nanotechnology**

UNIT - II	12hrs	
Self-Study	*RES Mechanisms, An overview colloidal Drug Delivery with respect to Physicochemical& Biopharmaceutical aspects*	

Targeting Methods: Molecular targets for cellular targeting, Ligands as delivery and targeting tools, Nano Particles, Liposomes, Solid Lipid nanoparticles: Types, preparation and evaluation. **Targeting in cancer and infectious diseases**

UNIT - III	12hrs	
Self-study	*Concept of Microencapsulation*	

Micro Capsules / Micro Spheres: Types, preparation and evaluation of Monoclonal Antibodies, Niosomes, Aquasomes, Phytosomes, Electrosomes, **Lipid Drug Conjugates, Theranostics**

UNIT - IV	12hrs	
Self-Study	*Anatomy and physiology of the respiratory system, Airway physiology and disposition patterns*	

Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers, Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation, **Factors affecting particle disposition in the lungs, Pulmonary receptor targeting, Strategies for enhancement in nasal absorption, Animal models for nasal absorption studies**

UNIT - V	12hrs	
Self-Study	*Gene Targeting Principles*	

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Bio-distribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Reference Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery- concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers &Distributors, New Delhi, First edition 1997 (reprint in 2001).

Course Code	ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS	L	T	P	C
23S03202		4	0	0	4
Semester		II			

Course Objectives:

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts

Course Outcomes (CO):

Upon completion of this course it is expected that students will be able to understand, • The basic concepts in biopharmaceutics and pharmacokinetics. • The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination. • The critical evaluation of biopharmaceutic studies involving drug product equivalency. • The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters. • The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics

UNIT - I	12hrs	
Self-Study	*Gastrointestinal tract, Mechanism of drug absorption*	

Drug Absorption from the Gastrointestinal Tract: Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in-vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. **Detailed discussion of the variety of transporters and the role of transporters in the GI tract and liver and their role in drug absorption, Discussion of the traditional and high-throughput approaches towards estimation of solubility, dissolution rate and drug absorption.**

UNIT - II	12hrs	
Self-Study	*Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance*	

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: in-vitro dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution Testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product, **Role of drug membrane interaction in pharmacokinetics & pharmacodynamics of drugs, Study of the drug membrane interactions, Automation in Dissolution.**

UNIT – III	12hrs	
Self-Study	*Basic considerations, pharmacokinetic models, compartment modeling*	

Pharmacokinetics: Basic considerations, one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. **Role of Pharmacokinetics in drug discovery; drug development and process, Metabolite Pharmacokinetics**

UNIT – IV	12hrs	
Self-Study	*Bioavailability and Bioequivalence Introduction, Purpose of bioavailability studies, relative and absolute availability*	

Drug Product Performance, In-Vivo: Bioavailability and Bioequivalence: drug product performance, Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, cross over study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. **Case studies and problem solving w.r.t. above including design of controlled release dosage forms and other novel drug delivery systems based on pharmacodynamic and pharmacokinetic rationale.**

UNIT – V	12hrs	
Self-Study	*Introduction, Proteins and peptides, Monoclonal antibodies*	

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs, **Individualization of dosage regimen, conversion from IV dosing to oral dosing, determination of dose, frequency of administration and route of administration, therapeutic drug monitoring, dosing of drug in infants and elders, variability in clinical response and pharmacokinetics w.r.t. renal and hepatic diseases.**

Reference Books:

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press. 6 Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.

Course Code	COMPUTER AIDED DRUG DELIVERY SYSTEM	L	T	P	C
23S03203		4	0	0	4
Semester		II			

Course Objectives:

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Course Outcomes (CO):

Upon completion of this course it is expected that students will be able to understand, • History of Computers in Pharmaceutical Research and Development • Computational Modeling of Drug Disposition • Computers in Preclinical Development • Optimization Techniques in Pharmaceutical Formulation • Computers in Market Analysis • Computers in Clinical Development • Artificial Intelligence (AI) and Robotics • Computational fluid dynamics (CFD)

UNIT - I	12hrs	
Self-Study	*Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development.*	

a. **Statistical modeling in pharmaceutical research and development:** Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling, Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

b. Computation tools for drug development- Ligand based and structure-based models.

UNIT - II	12hrs	
Self-Study	*Case Studies on in-silico models of drug absorption*	

Computational Modeling of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

UNIT - III	12hrs	
Self-Study	*Concept of optimization, Optimization parameters*	

Computer-aided formulation development: Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis, **Computational Methods for studying drug metabolism: Isolated enzymes, recombinant enzymes, subcellular fractions, hepatocytes, perfused liver, in-vivo drug metabolism studies**

UNIT – IV	12hrs	
Self-Study	*Case studies on simulation models for GI absorption*	

Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in-vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of

Computer Systems.		
UNIT – V	12hrs	
Self-Study	*Case studies on AI*	
Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.		
Reference Books:		

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Course Code	COSMETICS AND COSMECEUTICALS	L	T	P	C
23S03204		4	0	0	4
Semester		II			

Course Objectives:

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Course Outcomes (CO):

Upon completion of the course, the students shall be able to understand • Key ingredients used in cosmetics and cosmeceuticals. • Key building blocks for various formulations. • Current technologies in the market • Various key ingredients and basic science to develop cosmetics and cosmeceuticals • Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

UNIT - I	12hrs	
Self-Study	*Case Studies for regulatory approvals to cosmetics*	

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. **Packaging materials, specialty packages for cosmetics, labelling requirements for cosmetics.**

UNIT - II	12hrs	
Self-Study	*Structure of skin, Structure of hair*	

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm, **Advancements in formulation of cosmetics for hair and skin**

UNIT - III	12hrs	
Self-Study	*Novel excipients in Cosmetics*	

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndet bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT – IV	12hrs	
Self-Study	*Historical purview of perfumes, Approved colours as per Indian, European and US specifications*	

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. **BIS guidelines for quality of finished products for cosmetics.**

UNIT – V	12hrs	

Self-Study	*Discussion on Aleo vera, henna, tea tree oil, neem in various cosmetic products*	

Herbal Cosmetics: Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. **Safety and toxicity evaluation of cosmetic products, Current trends in use of herbal materials in cosmetics.**

Reference Books:

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4thedition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory

Course Code	NANO TECHNOLOGY & TARGETED DDS (NTDS) PRACTICALS - II	L	T	P	C
23S03205		0	0	6	3
Semester		II			

List of Experiments:

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands 8. Protein binding studies of a highly protein bound drug & poorly protein bound drug

Course Code	ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS	L	T	P	C
23S03206		0	0	6	3
Semester		II			

List of Experiments:

1. Bioavailability studies of Paracetamol in animals.
2. **Pharmacokinetic and IVIVC data analysis by Kinetica Software**
3. In vitro cell studies for permeability and metabolism
4. DoE Using Design Expert® Software
5. Formulation data analysis Using Design Expert® Software
6. Quality-by-Design in Pharmaceutical Development
7. **Establishment of IVIVC for a marketed formulation**
8. **Oral microemulsions/SMEDDS, ternary phase diagrams**
9. **Oral microemulsions/SMEDDS, ternary phase diagrams**
10. Development and evaluation of Creams
11. Development and evaluation of Shampoo and Toothpaste base
12. To incorporate herbal and chemical actives to develop products
13. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

AUDIT COURSE-I

Course Code	Audit Course – I	L	T	P	C
23DAC101a	SPIRITUALITY & VALUE EDUCATION	2	0	0	0
Semester		I			

Course Objectives: This course will enable students to learn

- To understand the nature and sources of values and disvalues.
- To emphasize the role of teacher as an agent of social change through value education
- To understand the effect of values in one's life.
- To preserve positive values and bring harmony between traditional and modern values.
- To acquaint students with the role of teachers, parents, society and nation in creating a value laden society.

Course Outcomes (CO): Student will be able to

Students will be able to

- Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

UNIT - I

Value education – Meaning nature and sources of values. Concept of value education, Need , importance & objectives of value education. Value education Vs Value-oriented education. Developing Spirituality, Virtues, Powers & Qualities, Daily Spiritual Study.

UNIT - II

Classification of values: Biological, socio-cultural and ecological determinants of values. Disvalues corresponding to values leading to faithlessness. Role of family, society and school in overcoming these negative values.

Meditation: Positive thinking & Emotional Maturity, Consciousness & the Divine

UNIT - III

Development of values as a personal and life long process. Teaching of values as an integral part of education. Role of teacher in value education. Synthesis between traditional and modern values.

Regularity & Punctuality-Revision in Day time- Sharing with others Becoming the Embodiment

UNIT - IV

Role of co-curricular activities in inculcating values among students. Effect of disvalues, overcoming negative values by means value education. Resolving conflict among values. Evaluation of values.

Selfless Service Different forms of Services-Values for selfless service-Balance of Independence & Co-operation- Efforts for Victory

UNIT - V

Values for Excellence in Life: In response to Living Values, Value adoption for Self-development, Value adoption in Family life, Value adoption in professional life.

Suggested Reading

1. Mulya shiksha ke Pariprekshya R.S. Pandey
2. Manav mulya evam shiksha R.A. Sharma
3. Human Values and Education R.A.Sharma
4. Value Education Yogesh kr. Singh and Ruchika Nath.
5. Mulyaparak shiksha aur Samaaj Natthulal Gupt

Course Code	DISASTER MANAGEMENT	L	T	P	C
23DAC101b		2	0	0	0

Semester	I

Course Objectives: This course will enable students:

- Learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.

Course Outcomes (CO): Student will be able to

- Develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- Critically understand the strengths and weaknesses of disaster management approaches
- Planning and programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction: Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude. Disaster Prone Areas in India: Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT - II

Repercussions of Disasters and Hazards: Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT - III

Disaster Preparedness and Management: Preparedness: Monitoring of Phenomena Triggering. A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT - IV

Risk Assessment Disaster Risk: Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation: Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

1. Disaster Management: Hazard and Risk Awareness – A Comprehensive Approach, N. V. S. Raju, BS Publications
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

AUDIT COURSE-3

Course Code	BASIC RESEARCH SKILLS	L	T	P	C
23DAC101c		2	0	0	0
Semester		I			

Course Objectives: This course will enable students:

- To identify the minimum set of skills, knowledge and key principles that would enable those with limited or no previous experience to undertake high-quality research for health.
- To equip with the necessary training in a broad range of research skills, with the express aim of preparing them for postgraduate level writing and research, and ultimately for their dissertation.

Course Outcomes (CO): Student will be able to

Students will be able to:

- Communicate the results of their work accurately, with well-structured and coherent arguments in an effective and fluent manner
- Demonstrate that they have mastered the intricacies of advanced academic writing
- Demonstrate their ability to conduct linguistic research using a range of research methods and tools.

UNIT - I

Introduction to Research and Research Design Nature and scope of research, information-based decision making and source of knowledge. The research process; basic approaches and terminologies used in research. Defining research question and framing of hypotheses, preparing a research plan, qualitative and quantitative research designs, Experimentation, Observational studies, Exploring secondary data.

UNIT - II

Data Source and Data Collection Field research; primary data collection from observations, surveys and experimentation.

UNIT - III

Measurement and scaling; commonly used scales in reliability and validity of scales. Designing instrument for data collection; testing the instrument, data collection process, Sampling methods and procedures and sample size decisions.

UNIT - IV

Editing and coding of data, tabulation, graphic presentation of data, cross tabulation, Testing of hypotheses; type I and II errors

UNIT - V

Report Writing and Presentation Need for Effective documentations, Importance of Report Writing, types of research reports Report structure, Report preparation and presentations, Tables, Graphs, Charts, Referencing etc.

Suggested Reading

- Saunders- Research Methods for Business Students - Pearson Education
- Research Methodology by D. K. Bhattacharyya – Excel
- Research Methodology by Kothari

AUDIT COURSE-II Sem (1)

Course Code	SIMULATION TOOLS FOR DRUG DESIGN	L	T	P	C
23DAC201a		2	0	0	0
Semester		**II**			

Course Objectives: This course will enable students

- To strengthen the skills in various software tools used in pharma research.

Course Outcomes (CO):

Students will be able to understand

- Handling and applications of software tools.

UNIT - I	
Tools for Drug development - Introduction	
UNIT - II	
Tools for Screening of Drug -Excipient Compatibility	
UNIT - III	
Applications of In-silico tools in drug development – Case studies	
UNIT - IV	
Hands on Training on In-Silico tools	
UNIT - V	
Computational tools for drug optimization	

Suggested Reading

1. Pharmaceutical Statistics by Dekker Series
2. Biophysical and Computational Tools in Drug Discovery by Saxena

AUDIT COURSE-II Sem (2)

Course Code	CUTTING EDGE TECHNOLOGIES IN PHARMACEUTICS	L	T	P	C
23DAC201b		2	0	0	0
Semester		II			

Course Objectives: This course will enable students:

- To be able to upskill the students in the advanced area of pharmaceutical research.

Course Outcomes (CO):

Students will be able to understand:

- Grasp the manufacturing of various APIs
- Understand the process flow diagram and various process parameters
- Identify and solve engineering problems during production
- Appreciate the importance of GMP, QA and RA departments in API industry

UNIT - I		
3D Printing of Pharmaceuticals		
UNIT - II		
Physiological Modelling of Pharmaceutical Dosage Forms		
UNIT - III		
Nanocomposites and Biosensors in drug delivery		
UNIT - IV		
Advances in Nanocarriers for drug delivery - Case Studies		
UNIT - V		
Theronostics and its applications in drug delivery		

Suggested Reading

1. Advanced Pharmaceutics – Decker Series
2. Advanced Drug Delivery – Ashim K. Mitra

AUDIT COURSE-II Sem (3)

Course Code	PILOT PLANT AND SCALE-UP TECHNIQUES FOR PHARMACEUTICAL DOSAGE FORMS.	L	T	P	C
23DAC201c		2	0	0	0
Semester		II			

Course Objectives: This course will enable students:

- To be able to upskill the students in the pilot plant and scale up techniques

Course Outcomes (CO):

Students will be able to understand:

- Grasp the manufacturing of various APIs
- Understand the process flow diagram and various process parameters
- Identify and solve engineering problems during production
- Appreciate the importance of GMP, QA and RA departments in API industry

UNIT - I

Pilot Plant General Considerations- including significance of personal requirements, space requirements, raw materials, pilot plant scale up considerations for solids, liquids and semi solids.

UNIT - II

Scale-up Techniques: for process research and development, optimization, maximization of productivity, in-process control techniques.

UNIT - III

Technology Transfer Protocols

UNIT - IV

Quality Management Systems – Concept of Quality, Total Quality Management, Quality by Design, Six Sigma Concept

UNIT - V

Case Studies on Scale up of Solids, Liquids and Semi-Solid Dosage Forms.

Suggested Reading

1. Industrail Pharmacy by N K Jain
2. Industrial Pharmacy by CVS Subramanyam

Course Code	RESEARCH METHODOLOGY AND BIOSTATISTICS	L	T	P	C
23DRM101		4	0	0	4
	Semester	III			

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes (CO): Student will be able to

At the end of this course, students will be able to

- Design robust studies using key research methodologies, including controls, randomization, and error reduction.
- Perform statistical tests and analyze research data to validate study outcomes.
- Ensure ethical integrity in medical research by applying principles like autonomy, beneficence, and informed consent.
- Follow CPCSEA guidelines for ethical laboratory animal care and facility management.
- Uphold the Declaration of Helsinki principles for ethical medical research involving human subjects.

UNIT - I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT - II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT - III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT - IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals

UNIT - V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.
Reference Books:
1. Stuart Melville and Wayne Goddard, “Research methodology: an introduction for science &engineering students’”
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”

Course Code	PUBLICATION ETHICS IN RESEARCH	L	T	P	C
23SPE301		3	0	0	3
	Semester	III			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Explain the fundamentals of ethics, moral philosophy, and the nature of moral judgments in research and science.
- Identify and evaluate issues such as falsification, fabrication, plagiarism, redundant publications, and data misrepresentation.
- Adhere to best practices in publication ethics, address conflicts of interest, and recognize unethical practices, including predatory journals and authorship violations.
- Employ software tools like Turnitin and Urkund to detect plagiarism and engage in discussions on ethical issues in research and publishing.
- Use indexing and citation databases and evaluate research impact using metrics such as h-index, g-index, and altmetrics.

UNIT - I		Lecture Hrs:10
Ethics: definition, moral philosophy, nature of moral judgements and reaction		

UNIT - II		Lecture Hrs:10
Ethics with respect to science and research 2. Intellectual honesty and research integrity 3. Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP) 4. Redundant publications: duplicate and overlapping publications, salami slicing 5. Selective reporting and misrepresentation of data.		

UNIT - III		Lecture Hrs:10
Publication ethics: definition, introduction and importance 2. Best practices /Standards setting initiatives and guidelines: COPE. WAME, etc., 3. Conflicts of interest 4. Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types 5. Violation of publication ethics, authorship and contributorship 6. Identification of publication misconduct, complaints and appeals 7. Predatory publishers and journals		

UNIT - IV		Lecture Hrs:9
Group Discussions 1. Subject specific ethical issues, FFP, authorship 2. Conflicts of interest 3. Complaints and appeals: examples and fraud from India and abroad B. Software tools Use of plagiarism software like Turnitin, Urkund and other open source software tools		

UNIT - V		Lecture Hrs:9
Databases 1. Indexing databases 2. Citation databases: Web of Science, Scopus, etc. B. Research Metrics 1. Impact Factor of Journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score 2.		

Metrics: h-index, g index, i10 index, altmetrics

Suggested Reading

1. Bird, A.(2006). Philosophy of Science.Routledge
2. Maclntyre, Alasdair (1967) A Short History of Ethics. London
3. P.Chaddah, (2018) Ethics in Competitive Research: Do not get Scooped; do not get Plagiarized, ISBN :978-9387480865
4. National Academy of Sciences, National Academy of Engineering and Institute of Medicine. (2009). On Being a Scientist: A Guide to responsible conduct in Research: Third Edition, National Academies Press.
5. Resnik, D.B.(2011) What is ethics in research & why is it important. National institute of Environmental Health Science, 1-10 Retrieved from https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm
6. Beall, J: (2012) Predatory publishers are corrupting open access. Nature, 489(7415), 179-179. https://doi.org/10.1038/489179a
7. Indian National Science Academy (INSA), Ethics in Science Education, Research and Governance (2019), ISBN:978-81-939482-1-7. htt://www.insaindia.res.in/pdf/Ethics_Book.pdf.Heidelberg London, 2011

Course Code	PROFESSIONAL BUSINESS SKILLS	L	T	P	C
23SOE302		3	0	0	0
	Semester	III			

Course Objectives:

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcomes (CO): Student will be able to

On completion of this course it is expected that students will be able to:

To update and expand basic Informatics skills of the students

To equip the students to effectively utilize the digital knowledge resources for their study

UNIT - I

Professionalism: Meaning -Definition – Characteristics – Traits and Qualities of a good professional – Professionalism in business – Professional Skills: important soft skills for business success- Professionalism in Communication: Verbal Communication: Professional Presentation – Different Presentation Postures- Written Communication: Email–Significance of Email in business – Email etiquette: format – rules – dos and don'ts – Technical

UNIT - II

E-Learning- Introduction of electronic learning – benefits and drawbacks of e-Learning – Online education – Digital age learners – Knowledge resources on internet – E-books, Audio, Video and other means for e-learning- Introduction to e-content development and tools – Online libraries – MOOCs – The e-Learning as a service Industry – major technologies used in e-earning- different approaches for e-Learning delivery – E-learning in India

UNIT - III

Business Data Analysis- Features of New Generation Computers – Concept of data analysis – Business Data Analysis – Data Analyst – Types of analysts – organisation and source of data, importance of data quality, dealing with missing or incomplete data- Social Networking Analysis – Big Data Analysis – Role of Data Scientist in Business & Society – Role of Artificial Intelligence and Intelligent Agents in e-business – Ethical and Legal considerations in Business Analytics

UNIT - IV

Budget planning and Implementation, barriers in budgeting, types of budget

UNIT - V

Digital Marketing : Introduction to Digital marketing Environment –meaning & Concept – Need for digital marketing – Advantages and disadvantages of digital marketing -Trends in digital marketing- Types of digital marketing – Business models in digital marketing

Reference Books:

1. Professional Business Skills – Lee Pelitz 2nd Edition
2. Peter Norton, Introduction to Computers, Tata McGraw Hill Private Limited, New Delhi, 2009.
3. Alan Evans, ITL ESL, Leslie Lamport, Dolores Etter, Darren George, Kenneth C Laoudon, Gary Rogers, Rainer Handel, INFORMATICS -Technology in Action, Pearson Education, Delhi, 2009.
4. V.Rajaraman, Introduction To Information Technology, PHI Learning Private Limited, New Delhi, 2009.

Course Code	IPR AND PATENTS	L	T	P	C
23SOE303		3	0	0	0
	Semester	III			

Course Objectives: This course will enable students:

1. To know the importance of Intellectual property rights, which plays a vital role in advanced Technical and Scientific disciplines
2. Imparting IPR protections and regulations for further advancement, so that the students can familiarize with the latest developments

Course Outcomes (CO): Student will be able to

1. IPR Laws and patents pave the way for innovative ideas which are instrumental for inventions to seek Patents
2. Student get an insight on Copyrights, Patents and Software patents which are instrumental for further advancements

UNIT - I

Introduction to Intellectual Property Rights (IPR): Concept of Property – Introduction to IPR – International Instruments and IPR – WIPO – TRIPS – WTO -Laws Relating to IPR – IPR Tool Kit – Protection and Regulation – Copyrights and Neighboring Rights – Industrial Property – Patents – Agencies for IPR Registration – Traditional Knowledge –Emerging Areas of IPR – Layout Designs and Integrated Circuits – Use and Misuse of Intellectual Property Rights.

UNIT - II

Copyrights and Neighboring Rights: Introduction to Copyrights – Principles of Copyright Protection – Law Relating to Copyrights – Subject Matters of Copyright – Copyright Ownership – Transfer and Duration – Right to Prepare Derivative Works –Rights of Distribution – Rights of Performers – Copyright Registration – Limitations – Infringement of Copyright – Relief and Remedy – Case Law – Semiconductor Chip Protection Act.

UNIT - III

Patents: Introduction to Patents – Laws Relating to Patents in India – Patent Requirements –Product Patent and Process Patent – Patent Search – Patent Registration and Granting of Patent – Exclusive Rights – Limitations – Ownership and Transfer — Revocation of Patent – Patent Appellate Board – Infringement of Patent – Compulsory Licensing — Patent Cooperation Treaty – New developments in Patents – Software Protection and Computer related Innovations

UNIT - IV

Trademarks: Introduction to Trademarks – Laws Relating to Trademarks – Functions of Trademark – Distinction between Trademark and Property Mark – Marks Covered under Trademark Law – Trade Mark Registration – Trade Mark Maintenance – Transfer of rights – Deceptive Similarities. Likelihood of Confusion – Dilution of Ownership – Trademarks Claims and Infringement – Remedies – Passing Off Action.

UNIT - V

Trade Secrets & Cyber Law and Cyber Crime: Introduction to Trade Secrets – General Principles – Laws Relating to Trade Secrets – Maintaining Trade Secret – Physical Security – Employee Access Limitation – Employee Conidentiality Agreements – Breach of Contract –Law of Unfair Competition – Trade Secret Litigation – Applying State Law. Cyber Law – Information Technology Act 2000 – Protection of Online and Computer Transactions – E-commerce – Data Security – Authentication and Confidentiality – Privacy – Digital Signatures – Certifying Authorities – Cyber Crimes – Prevention and Punishment – Liability of Network Providers.

Suggested Reading

1. Intellectual Property Rights (Patents & Cyber Law), Dr. A. Srinivas. Oxford University Press, New Delhi.
2. Deborah E.Bouchoux: Intellectual Property, Cengage Learning, New Delhi.
3. Prabhuddha Ganguli: Intellectual Property Rights, Tata Mc-Graw –Hill, New Delhi
4. Richard Stim: Intellectual Property, Cengage Learning, New Delhi.
5. Kompal Bansal & Parishit Bansal Fundamentals of IPR for Engineers, B. S. Publications (Press).
6. Cyber Law – Texts & Cases, South-Western's Special Topics Collections.
7. R.Radha Krishnan, S.Balasubramanian: Intellectual Property Rights, Excel Books. New Delhi.
8. M.Ashok Kumar and MohdIqbal Ali: Intellectual Property Rights, Serials Pub.